REMARKS

Upon entry of the foregoing amendments, claims 1–4, 10–14, 16, 18, 19, 25 and 26 are pending. Applicants have amended claims 3 and 4 to correct antecedent basis. Thus, claims 3 and 4 now recite "polynucleotides." Basis for these amendments can be found in the specification as originally filed, and in particular, in originally filed claims 1 and 2. Applicants have amended claim 13 to correct improper dependency. Thus, claim 13 now recites "the host cell of claim 12." Applicants have amended claim 19 to correct clerical errors and improper dependency. Thus, claim 19 now recites "the vaccine vector of claim 16." Applicants have amended claim 25 to correct clerical errors. Applicants have added new claims 38 and 39 to more accurately claim the present invention. New claims 38 and 39 further limit the type of host cells to be used in the present invention. Specifically, new claims 38 and 39 are directed to mammalian cells and human cells respectively. Basis for these amendments can be found in the specification as originally filed, and in particular, at pg. 14, lines 9–14; pg. 15, line 31; and in originally filed claim 17.

These amendments add no new matter.

Co–Pending Applications

Applicants acknowledge the Examiner's request regarding copies of claims, correlated with the serial number of the case in which they appear, for each pending application directed to the pending subject matter.

Applicants respectfully submit that acquiescing to the Examiner's request of providing copies of pending claims would be unduly onerous and expensive for Applicants. Applicants have **no obligation to provide the Examiner with copies of claims in any pending applications**. In fact, Applicants submit that, under M.P.E.P. §804, it is the Examiner's burden to identify any potential statutory and/or "obvious-type" double patenting rejections. *See*, M.P.E.P. §804(I)(B), which states:

> Occasionally, the **examiner** becomes aware of two copending applications filed by the same inventive entity, or by different inventive entities having a common

> inventor, and/or that are filed by a common assignee that would raise an issue of double patenting if one of the applications became a patent.

However, Applicants agree to provide the Examiner copies of the requested claims upon determination of allowable subject matter in the present application.

Drawings

Applicants acknowledge the Draftsperson's objection to the Drawings filed in the present application.

Applicants will provide formal drawings upon determination of allowable subject matter in the present application.

Oath/Declaration

Applicants acknowledge the Examiner's objection to the Declaration as filed in the present application. Applicants have enclosed herewith an executed Declaration. Accordingly, Applicants believe that the present objection is now moot.

Specification

The Examiner has objected to the Specification as having various informalities.

Applicants have amended the Specification to correct these informalities. Accordingly, Applicants believe that the present objection is now moot.

Provisional Double Patenting Rejection over Co-pending Applications

The Examiner has provisionally rejected claims 1–4, 10–14, 16–19, 25 and 26 under 35 U.S.C. §101 as claiming the same invention as that of claims 1, 20, 21, 25–28, 32–35, 41 and 42 of co-pending application U.S.S.N. 09/376,770 ("**'770**").

Applicants traverse. 37 CFR §1.78(b) provides that when two or more applications filed by the same Applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention

during pendency in more than one application. However, the M.P.E.P. clearly states that "[t]his paragraph is appropriate only when the conflicting claims are **patentably distinct**. See MPEP §822. *See also*, In re Zickendraht, 319 F.2d 225, 138 USPQ 22 (CCPA 1963) (where the Court held that the doctrine is well established in that claims in different applications need be more than merely different in form or content and that **patentable distinction must exist to entitle applicants to a second patent**).

The **'770** application is a co-pending application having the both the same inventive entity and assignee. However, both applications are directed to distinct sequences encoding ***different*** *Chlamydia* polypeptides. Applicants have attached herewith an alignment comparison between the polypeptide of the present application with those disclosed by U.S.S.N. 09/376,770 (Exhibits A and B). The comparisons clearly show that the polypeptides according to the present invention are **completely different** from those disclosed in the **'770** application.

Accordingly, in light of the arguments above, Applicants respectfully request reconsideration and withdrawal of the present provisional double patenting rejection.

35 U.S.C. §112, First Paragraph Rejections

The Examiner has rejected claims 1–4, 10–14, 16–19, 25 and 26 under 35 U.S.C. §112, first paragraph as containing subject matter which was not described in the Specification in such a way as to enable one skilled in the art to make and/or use the invention, stating that the Specification is not enabled for a polynucleotide encoding a polypeptide having a sequence that is "at least 75% homologous" to SEQ ID NO:2 and "functional fragments thereof." Specifically, the Examiner has alleged that:

> Without a clear and unambiguous description of how to perform the comparison, the scope of the claims can not be envisaged (*sic*). Without a specific disclosure of the parametric values used in the algorithm, the sequence identity between two sequences has no common meaning within the art and therefore, one of ordinary skill in the art cannot be sure of the sequences embraced by the claims and would not be able to make and use those polynucleotide or polypeptide sequence homologs as recited in the instant claims, without undue experimentation.

See e.g., December 13, 2000 Office action at pg. 5.

Applicants traverse. Methods and computational programs for conducting sequence comparisons for homology are well known within the art. Homology is typically measured using **sequence analysis software** (*e.g.*, Sequence Analysis Software Package of the Genetics Computer Group, University of Wisconsin Biotechnology Center, 1710 University Avenue, Madison, WI 53705). Similar amino acid sequences are aligned to obtain the maximum degree of homology (*i.e.*, identity). To this end, it may be necessary to artificially introduce gaps into the sequence. Once the optimal alignment has been set up, the degree of homology (*i.e.*, identity) is established by recording all of the positions in which the amino acids of both sequences are identical, relative to the total number of positions.

The Specification also describes a preferred method for determining amino acid similarities, including amino acid sequence homology:

> One particularly preferred method of determining amino acid similarities is the PAM250 matrix described in Dayhoff et *al.*, *5* ATLAS OF PROTEIN SEQUENCE AND STRUCTURE 345-352 (1978 & Supp.), incorporated by reference herein. A similarity score is first calculated as the sum of the aligned pairwise amino acid similarity scores. Insertions and deletions are ignored for the purposes of percent homology and identity. Accordingly, gap penalties are not used in this calculation. The raw score is then normalized by dividing it by the geometric mean of the scores of the candidate compound and the reference sequence. The geometric mean is the square root of the product of these scores. The normalized raw score is the percent homology.

See e.g., Specification at pg. 9, lines 15–23. Furthermore, the Specification specifically and clearly defines a "homologous amino acid sequence" as:

> an amino acid sequence that differs from an amino acid sequence shown in SEQ ID NO: 2, only by one or more conservative amino acid substitutions, or by one or more non-conservative amino acid substitutions, deletions, or additions located at positions at which they do not destroy the specific antigenicity of the polypeptide. Preferably, such a sequence is at least 75%, more preferably 80%, and most preferably 90% identical to an amino acid sequence shown in SEQ ID NO: 2. Homologous amino acid sequences include sequences that are identical or substantially identical to an amino acid sequence as shown in SEQ ID NO: 2.

Id at pg. 8, lines 21–29. The Specification also describes amino acid sequence identity and conservative substitutions as:

> By "amino acid sequence substantially identical" is meant a sequence that is at least 90%, preferably 95%, more preferably 97%, and most preferably 99% identical to an amino acid sequence of reference and that preferably differs from the sequence of reference, if at all, by a majority of conservative amino acid substitutions. Conservative amino acid substitutions typically include substitutions among amino acids of the same class. These classes include, for example, (a) amino acids having uncharged polar side chains, such as asparagine, glutamine, serine, threonine, and tyrosine; (b) amino acids having basic side chains, such as lysine, arginine, and histidine; (c) amino acids having acidic side chains, such as aspartic acid and glutamic acid; and (d) amino acids having nonpolar side chains, such as glycine, alanine, valine, leucine, isoleucine, proline, phenylalanine, methionine, tryptophan, and cysteine.

Id at pg. 9, lines 8–14. Thus, Applicants assert that one of ordinary skill in the art could make and use such homologous sequences in, for example, vaccines and diagnostic reagents. Accordingly, Applicants respectfully request reconsideration and withdrawal of the present rejection.

35 U.S.C. §112, Second Paragraph Rejections

The Examiner has rejected claims 3, 4, 13, 17 and 19 under 35 U.S.C. §112, second paragraph, as being indefinite for improper antecedent basis.

Applicants have amended claims 3 and 4 to correct antecedent basis. Thus, claims 3 and 4 now recite "polynucleotides." Basis for these amendments can be found in the specification as originally filed, and in particular, in originally filed claims 1 and 2. Applicants have amended claim 13 to correct improper dependency. Thus, claim 13 now recites "the host cell of claim 12." Applicants have amended claim 19 to correct improper dependency. Thus, claim 19 now recites "the vaccine vector of claim 16." Applicants have added new claims 38 and 39 to more accurately claim the present invention. New claims 38 and 39 further limit the type of host cells to be used in the present invention. Specifically, new claims 38 and 39 are directed to mammalian cells and human cells respectively. Basis for these amendments can be found in the specification as originally filed, and in particular, at pg. 14, lines 9–14; pg. 15, line 31; and in originally filed claim 17.

In light of the above amendments, Applicants believe that the present rejections are now moot. Accordingly, Applicants respectfully request reconsideration and withdrawal of the present rejections.

35 U.S.C. §102 Rejection

The Examiner has rejected claims 1–4, 10–13, 16–19, 25 and 26 under 35 U.S.C. §102(b) as being anticipated by Longbottom *et al.* (**Longbottom**). Specifically, the Examiner has stated that **Longbottom** teaches "*chlamydial* genes or sequences coding for highly immunogenic protein fragments comprising 8 or 9 amino acid residues."

Applicants traverse. **Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration**. *W.L. Gore & Associates v. Garlock, Inc.*, 220 USPQ 303, 313 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984); *Connell v. Sears Roebuck & Co.*, 220 USPQ 193, 198 (Fed. Cir. 1983); *Verdegaal Bros. v. Union Oil Co. of California,* 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); *In re Spada*, 15 USPQ2d 1655 (Fed. Cir. 1990); MPEP § 2131. "**There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention.**" *Scripps Clinic & Research Foundation v. Genentech Inc.*, 18 USPQ 2d 1001, 1010 (Fed. Cir. 1991).

Although both applications are directed to *Chlamydia* polypeptides, **Longbottom** discloses distinct sequences encoding ***different*** *Chlamydia* polypeptides. Applicants have attached herewith an alignment comparison between the polypeptides of the present application with those disclosed by **Longbottom** (Exhibit C1 to C4). Applicants have highlighted the regions that the Examiner has suggested would be identical between the present application and **Longbottom** . As can be seen by the highlighted regions, the rejection seems to be based upon that of identical fragments within the polynucleotides and/or polypeptides of the present invention, **not on the *entire* polynucleotide or polypeptide.** Furthermore, the comparisons clearly show that the polynucleotides and polypeptides according to the present invention are, in

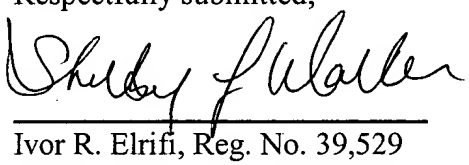
fact, **different** from those disclosed in **Longbottom**. Thus, Applicants assert that the present application is not anticipated by **Longbottom.**

Accordingly, in light of the arguments above, Applicants respectfully request reconsideration and withdrawal of the present rejection.

CONCLUSION

On the basis of the foregoing amendments and remarks, Applicants respectfully submit that the pending claims are in condition for allowance. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

On pg. 7, line 10, please delete "FIG. 1" and insert --FIG. 1A to 1I--.

On pg. 7, line 13, please delete "FIG. 2" and insert --FIG. 2A to 2H--.

On pg. 16, line 17, please delete "Rockville, Maryland" and add -- 10801 University Boulevard, Manassas, VA 20110-2209 --.

In the Claims:

3. (Amended) The polynucleotide of claim 2 wherein the fusion polypeptide is a heterologous signal peptide.

4. (Amended) The polynucleotide of claim 2 wherein the polynucleotide encodes a functional fragment of the polypeptide having the SEQ ID NO: 2.

13. (Amended) The host cell of claim 12[0], wherein said host cell is a prokaryotic cell.

19. (Amended) A pharmaceutical composition, comprising an immunologically effective amount of the vaccine vector of claim 16[4].

25. (Amended) A polynucleotide probe reagent capable of detecting the presence of *Chlamydia* in a biological material, comprising a polynucleotide that hybridizes to the polynucleotide of claim 1 under stringent conditions.

--38. (New) The host cell of claim 14, wherein said eukaryotic cell is a mammalian cell.

39. (New) The host cell of claim 38, wherein said mammalian cell is a human cell.--

EXHIBIT A - The Alignment of CPN100394 (SEQ ID NO: 13 in U.S.S.N. 09/376,770) to CPN 100396 (SEQ ID NO:1)

```
 GAP of: cpn394  check: 1192  from: 1  to: 903

WPDEF cpn100394 98kda protein
19721-006

 to: 396prt.pep  check: 2118  from: 1  to: 928
WPDEF
396prt
 Symbol comparison table: /big1/gcg/gcgcore/data/rundata/blosum62.cmp
 CompCheck: 1102
BLOSUM62 amino acid substitution matrix.
Reference: Henikoff, S. and Henikoff, J. G. (1992). Amino acid
           substitution matrices from protein blocks.  Proc. Natl. Acad.
           Sci. USA 89: 10915-10919.

      Gap Weight:      8      Average Match:  2.778
   Length Weight:      2   Average Mismatch: -2.248

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cpn394 x 396prt.pep       March 12, 2001 11:22  ..

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                .         .         .         .         .
     11 GTTYSLTGEV.LYIDPGKGGSITGTCFVETAGDLTFLGNGNTLKFLSVDA 59
        ||||   | | |   || | .|| .||.| ||||| ||||.| | .|||
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     60 GANIAVAHVQGS...KNLSFTDFLSLVITESPKSAVTTGKGSL.VSLGAV 105
        |  :| | |  |    |. .|  | ||    || |.:|||||..  | |..
    101 g.tvagaavnssvvdksttfigfsslsfiaspgssittgkgavscstgsl 149
                .         .         .         .         .
    106 QLQDINTLVLTSNASVEDGGVIKGNSCLIQGIKNSAIFGQNTSSKKGGAI 155
         |    .|. . | | :.|| |   .  : |   ||:| :||||||||||
    150 sltknvsllfsknfstdnggaitaktlsltgttmsalfsentsskkggai 199
                .         .         .         .         .
    156 STTQGLTIENNLGTLKFNENKAVTSGGALDLGAASTFTANHELIFSQNKT 205
         |.  |||  | | . |.:| .  || |:   |. | . | .. |  ||
    200 qtsdaltitgnqgevsfsdntssdsgaaifteasvtisnnakvsfidnkv 249
                .         .         .         .         .
    206 SGNAANGGAINCSGDLTFTDNTSLLLQENSTMQDGGALC....STGT.IS 250
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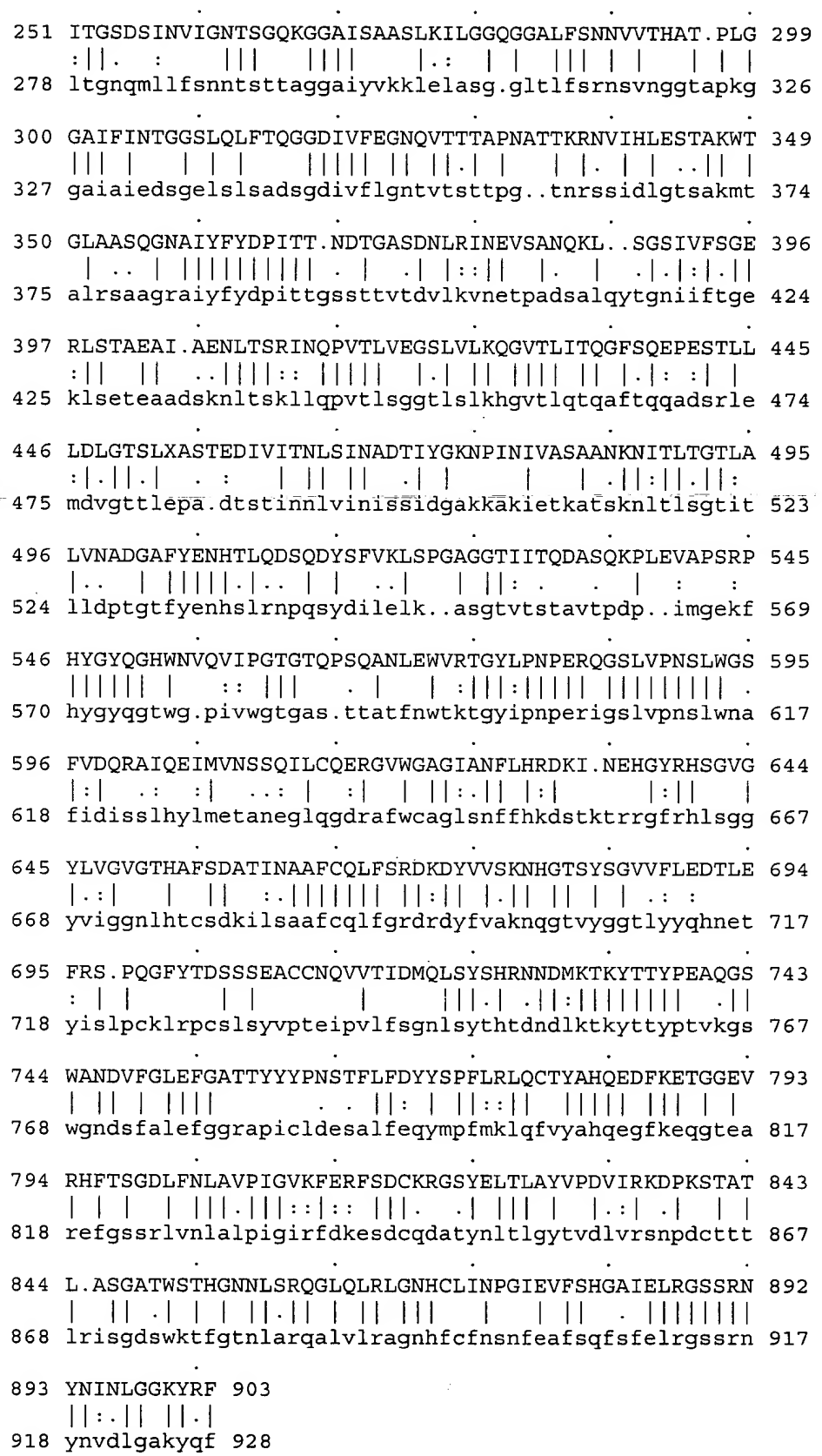
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868 lrisgdswktfgtnlarqalvlragnhfcfnsnfeafsqfsfelrgssrn 917
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EXHIBIT B - The Alignment of CPN100395 (SEQ ID NO: 15 in U.S.S.N. 09/376,770) to CPN 100396 (SEQ ID NO:1)

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 GAP of: cpn395  check: 1283  from: 1  to: 920

WPDEF cpn100395 98 kda protein
19721-006

 to: 396prt.pep  check: 2118  from: 1  to: 928

WPDEF
396prt

 Symbol comparison table: /big1/gcg/gcgcore/data/rundata/blosum62.cmp
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BLOSUM62 amino acid substitution matrix.
Reference: Henikoff, S. and Henikoff, J. G. (1992). Amino acid
           substitution matrices from protein blocks.  Proc. Natl. Acad.
           Sci. USA 89: 10915-10919.

        Gap Weight:      8      Average Match:  2.778
     Length Weight:      2   Average Mismatch: -2.248

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cpn395 x 396prt.pep        March 12, 2001 11:19  ..

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      1 mkssfpkfvfstfaifplsmi....atetvldssasfdgn.kngnfsvre 45
                .         .         .         .         .
     51 ATSDASGTTYILDGDVSISQ.AGKQTSLTTSCFSNTAGNLTFLGNGFSLH 99
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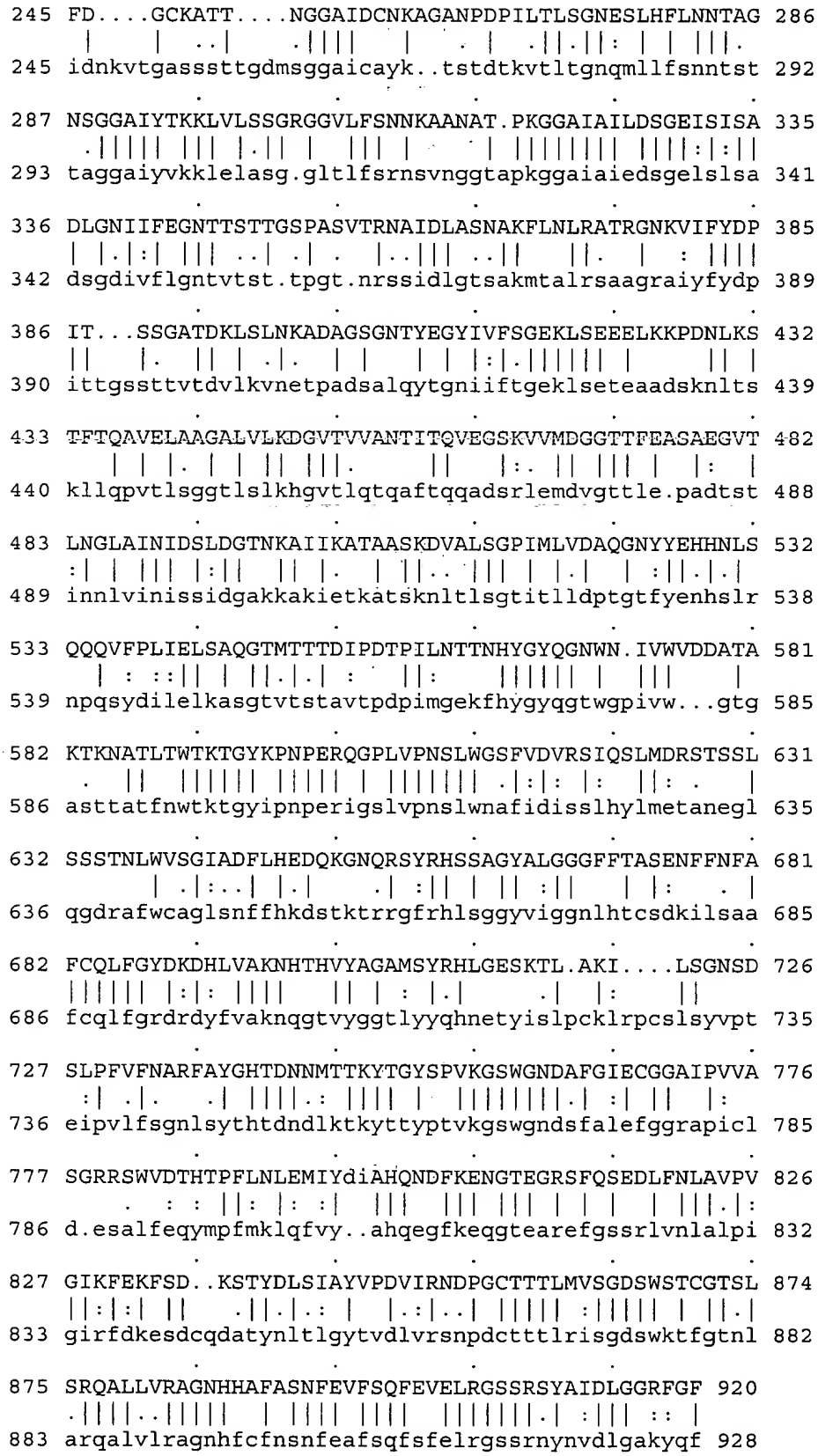
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